

**SUMMARY OF THE
SCOPE OF ACCREDITATION MEETING
JUNE 27, 2000**

A joint meeting of the Regulatory Coordination, Program Policy and Structure, Proficiency Testing, and Accrediting Authority Committees of the National Environmental Laboratory Accreditation Conference (NELAC) took place on Tuesday, June 27, 2000, at 11:30 a.m. Eastern Daylight Time (EDT) as part of the Sixth NELAC Annual Meeting in Williamsburg, VA. The meeting was led by Dr. Michael Miller, chair of the Regulatory Coordination Committee, Dr. Marcia Davies, chair of the Program Policy and Structure Committee, and Ms. Barbara Burmeister, chair of the Proficiency Testing Committee. A list of participants is given in Attachment A. *The purpose of the meeting was to discuss scope of accreditation and consistency issues.*

INTRODUCTION

Dr. Marcia Davies reviewed ground rules for the meeting. Dr. Miller then reviewed Chapter 1, Figure 1-3 (NELAC Tiered Scope of Accreditation) and definitions for each of the terms used in the figure.

PROPOSED CHANGES FROM THE REGULATORY COORDINATION COMMITTEE

Mr. George Avery then discussed proposed changes to Chapters 1, 2, and 4 from the Regulatory Coordination (RC) Committee for restructuring of the NELAC Fields of Testing (see Attachment B). A handout of the presentation materials (taken from the RC Committee minutes on December 16, 1999) was also distributed to participants.

Mr. Avery said that the RC Committee proposes that the NELAC Scope of Accreditation be defined by matrix and test method (using the NELAC glossary definition of “test method”). He said that the basic concept of their proposal is to change from “program-method-analyte” to “matrix-method.” Mr. Avery said that accreditation by “analyte” causes reciprocity problems. It is rare to find states with identical analyte lists for methods. The NELAC definition of “test method” is generic enough to accommodate both performance-based method systems (PBMS) and mandatory method situations. He also said that accreditation by “matrix” is critical to data quality. This proposal would require the development of a glossary definition for “matrix” and specific lists of analytes contained within the matrices.

ENVIRONMENTAL LABORATORY ADVISORY BOARD (ELAB) RECOMMENDATIONS

Mr. Jerry Parr presented the report from the ELAB Scope of Accreditation Workgroup. Based on the ILAC-G4 document, his workgroup recommends changing from “field of testing” to “scope of accreditation.”

Stakeholder Needs

- consistent and complementary to the Proficiency Testing requirements

- allow for flexibility under PBMS
- allow states to implement effectively
- provide appropriate information about a laboratory's capability
- allow for ease for reciprocal accreditations
- allow for current system where U.S. Environmental Protection Agency (EPA) has approved methods in Part 136 and 141
- ease of management, especially considering the national database

Mr. Parr recognized that PT is an important component of accreditation, but there does not need to be a one-to-one correlation of PT samples and analytes to scope of accreditation. He said that PT samples could include representative indicator analytes, as determined by the NELAC PT Committee.

EPA Program Requirements

- Should be a requirement that a laboratory has a system to ensure regulatory requirements/customer needs are met.
- Section 5.5.2.i should be reworded to read “mechanisms for ensuring that the laboratory reviews all new work, including the EPA and/or state regulatory requirements, to ensure that it has the appropriate facilities and resources before commencing such work.”
- Therefore, the EPA program does not need to be included within the scope.

Options Available

Option 1: Program-Method-Analyte (current system)

Option 2: Method (laboratory SOP)

Option 3: Technology (e.g., GC/MS)

Option 4: Analyte Class (e.g., volatiles)

Option 5: Scientific Discipline (e.g., chemistry)

Mr. Parr reviewed the advantages and disadvantages for each of these options (see Attachment C).

OPEN DISCUSSION

Dr. Davies then opened discussion for comments or alternative options from participants.

Many comments were provided by participants. These are summarized below:

- Accreditation by analyte is beneficial to small laboratories who only analyze a limited number of analytes.
- Many states require accreditation by analyte (e.g., NY, NJ, KS).
- Some preferred accreditation by matrix-method with a list of indicator compounds because variations in analyte lists may force laboratories to use multiple accrediting authorities.
- Several requested flexibility in accreditation (e.g., use methodology for microbiology and analytes for metals).
- Suggestion was made to use analyte class or specific analytes depending on the laboratory's needs.
- There was a suggestion to use 80% acceptance criteria on PTs – this should apply only to volatile organic compounds (VOCs).
- Concentration ranges must be included because it is critical for laboratories to demonstrate capability. Whether every analyte is covered is not as important as whether the laboratory can perform a certain method. In addition, laboratories should demonstrate that the method works for its intended application.
- Participant recommended going to “program-matrix-method-analyte” to be consistent with proposed PT fields of testing.
- Recommendation for “program-matrix-method-analyte/analyte class.” “Analyte” only works for inorganics, so add “analyte class” for organics. It can be a nightmare for laboratories, states, and clients to accredit by analyte.
- Matrix needs to be redefined for cost savings in PT (e.g., aqueous and drinking water can be defined as just water).
- Accreditation by analyte class may cause reciprocity issues because analyte lists may differ between AAs. The more permutations created, the greater laboratory's need for multiple AAs to meet reciprocity needs.
- Matrix-method-analyte class should be representative. For a PT, a laboratory does not have to analyze for every analyte, every method.
- Analyte classes and analytical technique need to be defined.
- If accredited by analyte class, it is the responsibility of the laboratory to document proficiency in the analysis of specific analytes.
- It is the client's responsibility to make sure the laboratory meets the needs of their specific projects. NELAC is not supposed to replace the responsibilities of the project officer. NELAC will accredit to a determined level, it will not meet the total requirements of every client.
- A laboratory may be forced to add analytical methods if all analytes in a class are required for accreditation and the method used by the laboratory is not offered by the AA.
- Several participants expressed the need for the AAs to have a consensus list of analytes.

- It was asked whether EPA can do without “program.” A representative from EPA’s Office of Water said that there are some good proposals on the floor, but they would need to see some exact proposals. They might have a problem with state laboratories trying to do self-certification.
- Comment was made that representation from small laboratories is lacking at NELAC. Most of them have a “wait-and-see” attitude. Concern was expressed that the standards are becoming increasingly complex which may hinder small laboratory participation.
- One of the AAs said that in their experience the small laboratories were having no more difficulty than the large laboratories.
- Analyte class needs to be defined in the NELAC Standards.
- We cannot afford to lose linkage to the current Drinking Water Program. Need to compare to the SDWA regulations.
- Several participants requested a “minimum list,” however the AAs tried to create such a list. Each program has some constraints on the list of analytes which prevented achievement of consensus.
- It was stated that to have reciprocity, NELAC will have to drop the analyte list.
- Another comment was made that the AAs list of analytes could continue to expand and the secondary AAs could accept it.
- It is essential to accredit by analyte—new Board of Directors policy will assist in reciprocity.
- All that the laboratories are really asking for is a uniform scope of accreditation. Need to identify what can be offered under a NELAC accreditation.
- Carl Kircher reminded participants that there is a spreadsheet on the website (discussed at last interim meeting) that compares the methods and analytes offered by the 11 AAs. He said that this should meet what most people are looking for.
- Comment was made that all states, not just the AAs, are involved in NELAC. They should be considered when developing a minimum analyte list.

It is clear that the scope of accreditation issues are complicated. A participant said that programmatic changes will have to be made and states will need to look at their own policies. These kinds of issues will delay changes to the NELAC standards. Realistically, there will not be a good proposal put forth on these changes until the next interim meeting (and for vote in 2001).

STRAW POLLS

Before adjourning the meeting, two straw polls were taken. Dr. Miller took a straw poll of the three major options discussed. Results were:

- matrix-method (29 votes)
- matrix-method-analyte/analyte class (90 votes)
- program-method-analyte (7 votes)

Ms. Burmeister took a straw poll on whether to make changes in the Proficiency Testing Standards from “program-matrix-analyte” to “program-method-matrix-analyte.” She explained that the committee’s intent was that the same PT sample can be used for multiple methods. This would be an interim step to make the PT scope more closely match the current NELAC program-method-analyte scope of accreditation. Right now this applies only to drinking water, but the committee would like to extend it to everything.

Results of this vote were:

- Yes (99 votes)
- No (26 votes)

**PARTICIPANTS
SCOPE OF ACCREDITATION MEETING
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Name	Affiliation	Address
Miller, Michael Chair of Regulatory Coordination	NJ DEP	T: (609)292-3950 F: (609)777-1774 E: Mmiller@dep.state.nj.us
Avery, George Regulatory Coordination Committee	AR Dept. of Health	T: (501)671-1429 F: (501)661-2468 E: ghavery@mail.doh.state.ar.us
Burmeister, Barbara Chair of Proficiency Testing	Wisconsin State Laboratory of Hygiene	T: (608)265-1100 F: (608)265-1114 E: burmie@mail.slh.wisc.edu
Davies, Marcia Chair of Program, Policy & Structure	US Army Corps of Engineers	T: (402)697-2555 F: (402)697-2595 E: marcia.c.davies@usace.army.mil
Parr, Jerry ELAB	Catalyst Info. Resources, LLC	T: (303)670-7823 F: (303)670-2964 E: catalyst@eazy.net
Lloyd, Jennifer (Contractor Support)	Research Triangle Institute	T: (919)541-5942 F: (919)541-5929 E: jml@rti.org
Leinbach, Adrienne (Contractor Support)	Research Triangle Institute	T: (919)541-6366 F: (919)541-7386 E: aal@rti.org

**Proposed Changes to Scope of Accreditation
by the Regulatory Coordination Committee**

Concept

Change from Program-Method-Analyte to Matrix-Method

- “Analyte” causes reciprocity problems - rare to find states with identical analyte lists for methods
- NELAC definition of “test method” is generic enough to accommodate both PBMS and mandatory method situations.
- “Matrix” is critical to data quality. Need glossary definitions/lists of defined matrices.

Proposed changes to the Program Policy and Structure Standard

- Delete Glossary Definition of “Fields of Testing”
- Add “Scope of Accreditation” “NELAC’s approach to accrediting laboratories by matrix and method”
- Replace Section 1.8.1 with:

“The accreditation process will be based on test method and matrix. The laboratory will meet the general requirements of Chapter 5, and the specific quality assurance requirements for the type of testing as outline in Chapter 5. Accreditation will be granted for the matrix and method, for example, Water-Method 525.2.

The laboratory must meet all relevant program requirements for the specific program for which a sample is analyzed.

Accreditation for a method will include all the analytes designated as within the scope of the method as well as other analytes which can be reasonably and legally analyzed by the method, and for which the laboratory can successfully demonstrate capability.”

- Delete Table 1.3
- Add to Section 1.6.5.1.4

“The Committee develops a list of analytes relevant to each approved test method for inclusion in proficiency tests, and criteria for the evaluation of laboratory performance on proficiency tests.”

Changes to Proficiency Testing Standard

- Add to Chapter 2, 2.7.1

“A grade of Acceptable is awarded when a laboratory successfully analyzes 80% of the analytes defined for a method.”

Changes to Accreditation Process Standard

- Replace “Program-matrix-analyte” with “matrix-method” in 4.1.4a, 4.1.4b, 4.1.4c, and 4.1.4d
- Replace “method” with “analyte”, “analyte” with “matrix”, and “matrix” with “method” in 4.1.4c

General Changes

- Replace “Fields of Testing” with “Scope of Accreditation” wherever it occurs in the standards.

ELAB Recommendations for NELAC Fields of Testing

Option 1: Program-Method-Analyte

Advantages:

- Most complete description of the laboratory's accredited testing capability.
- Accommodates EPA and state regulatory structures.
- Responds to marketplace client demands, which routinely ask if a laboratory is certified for a particular analyte.
- Can allow for the incorporation of PBMS.

Disadvantages:

- Extremely complex.
- Many possible combinations of specific programs, test methods, and analytes.
- Does not match the NELAC-defined fields of testing for PT.
- Does not allow changes to be incorporated in a timely fashion, as when EPA approves new analytes and/or methods.
- Does not address all the work performed by a laboratory, but only those methods and analytes which the AA elects to approve.

Option 2: Method

Advantages:

- Allows for existing EPA water program of approved methods.
- Allows for PBMS.
- Can be managed in a database, but will be complicated.
- Provides adequate information about a laboratory's capability.
- Easy for states to implement.
- Reciprocity is not an issue.
- Easier to audit because analytes are not included.

Disadvantages:

- Does not fully describe lab capability (analytes missing).
- Will need significant effort to coordinate/mesh with PT program.
- Will require some change on how states audit.
- Some states might have to go to analyte level because of regulations.

Option 3: Analyte Technique

Advantages:

- Simple for on-site assessment and national database.
- Easy to grant reciprocity.
- Allows for modification of methods or implementation of new methods under accredited analytic techniques.
- Allows implementation of PBMS.

Disadvantages:

- Not compatible with current drinking water requirements requiring accreditation by method.
- Not compatible with current proficiency testing requirements, program/matrix/analyte.

- Does not provide much information as to the actual capabilities of the laboratory.
- Requires the AA to “approve” list of approved techniques.

Examples of Issues:

- GC/MS volatiles: ion trap, SIM, HRMS
- ICP: radial vs. axial issue

Option 4: Analyte Class

Advantages:

- The scope of accreditation is short and easily managed by the national database.
- The short list makes reciprocity between accrediting agencies more likely.
- It provides for the incorporation of PBMS.
- It allows for the use of alternative methods.
- Laboratory on-site assessments are more manageable.
- Changes can be made in a timely fashion when new EPA analytes and methods are approved.

Disadvantages:

- Very little detail on the laboratory’s real testing capability.
- Some require different technologies.
- Incompatible with PT program (pass/fail criteria).
- Does not accommodate the current EPA and state regulatory structures.
- Does not meet the requirements of some permits or QAPPs.
- Issue with how to define classes.

Option 5: Scientific Discipline

Advantages:

- Reciprocity easiest of all options.
- Database management easiest of all options.
- PBMS easiest of all options

Disadvantages:

- Virtually no description of lab capability.
- No connection to PT samples.
- Diminished value of NELAC accreditation.